Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

October 12, 2001

Via Federal Express

Our Reference: 2951971

MQSA Facility ID: 164061
Inspection ID: 1640610006

Rosemary McFadden
Mammography Technologist
Welch Road Imaging
1101 Welch Road, Suite C-3
Palo Alto, CA 94304

Dear Rosemary McFadden,

We are writing to you because on September 25, 2001, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

1. Failed to produce documents verifying that the radiologic technologist [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA-approved body.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation

of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. Medical audit and outcome analysis was not done separately for each individual at site Welch Road Imaging.

2. Medical audit and outcome analysis was not done for the facility as a whole at site Welch Road Imaging.

3. Failed to produce documents verifying that the interpreting physician [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

4. The mammography equipment evaluation (by a medical physicist) for unit 2, [redacted] Mammography Room 1 was not done.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

Please submit your response to:

Russell A. Campbell, Compliance Officer
San Francisco District
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

**This note is not applicable for letters which also address patient notification*

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell at 510-337-6861.

Sincerely yours,

Charles D. Moss, Acting DD

for Dennis K. Linsley
District Director